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Frank C. Eisenschenk, Ph.D., Patent Attorney

INFORMATION DISCLOSURE STATEMENT Patent Application Docket No. SER-104 Serial No. 10/553,135

## IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

**Applicant** 

Giampiero de Luca

Serial No.

10/553,135

Filed

October 14, 2005

Conf. No.

1670

For

Interferon Beta in Severe Acute Respiratory Syndrome (SARS)

Mail Stop PCT Commissioner for Patents P.O. Box 1450 Alexandria, VA 22313

## INFORMATION DISCLOSURE STATEMENT UNDER 37 CFR §§1.97 AND 1.98

Sir:

In accordance with 37 CFR §1.56, the references listed on the attached form PTO/SB/08 are being brought to the attention of the Examiner for consideration in connection with the examination of the above-identified patent application. A copy of each cited reference is enclosed. However, Applicant has not submitted copies of the published U.S. Patent Applications cited on attached Form PTO/SB/08 pursuant to 37 CFR 1.98(a)(2)(ii).

It is respectfully requested that the references cited on the attached form PTO/SB/08 be considered in the examination of the subject application and that their consideration be made of record.

Docket No. SER-104 Serial No. 10/553,135

Applicant respectfully asserts that the substantive provisions of 37 CFR  $\S\S1.97$  and 1.98 are met by the foregoing statement.

Respectfully submitted,

Frank C. Eisenschenk, Ph.D.

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Attachments: Form PTO/SB/08; copies of cited references

Copy of International Search Report.

Approved for use through 07/31/2006. OMB 0651-0031

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Substitute for fo	orm 1449A/PTO			Complete if Known		
INICODM	ATION DISC	N 00	UDE	Application Number	10/553,135	
	ATION DISC ENT BY AP			Filing Date	October 14, 2005	
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				Examiner Name	not yet assigned	
Sheet	1	of	3	Attorney Docket Number	SER-104	

U.S. PATENT DOCUMENTS						
Examiner Initials*	Cite No. 1	Document Number Number - Kind Code <sup>2</sup> (if known)	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear	
	U1	US-2005/0137154	06-23-2005	Carter <i>et al</i> .	All	
	U2	US-2006/0035859	02-16-2006	Carter <i>et al</i> .	All	
	U3	US-				
	U4	US-				
	U5	US-				
	U6	US-				
	U7	US-				
_	U8	US-				
	U9	US-				

	FOREIGN PATENT DOCUMENTS							
Examiner Initials*	Cite No. <sup>1</sup>	Foreign Patent Document  Country Code <sup>3</sup> - Number <sup>4</sup> - Kind Code <sup>5</sup> (if known)	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear	Τ°		
	F1	WO 2005/009337	02-03-2005	HEMISPHERX BIOPHARMA	All			
	F2	WO 2004/100980	11-25-2004	VIRAGEN, INC.	All			
	F3	WO 03/031587	04-17-2003	THE REGENTS OF THE UNIVERSITY OF CALIFORNIA	All			
_	F4	EPO 1 213 029	06-12-2002	SCHERING CORPORATION	All			
	F5							
	F6							
	F7							

Examiner	Date
Signature	Considered

<sup>\*</sup>EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant. Applicant's unique citation designation number (optional). See Kind Codes of USPTO Patent Documents at <a href="https://www.uspto.gov">www.uspto.gov</a> or MPEP901.04. Enter Office that issued the document, by the two-letter code (MPO Standard T.3). For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. Kind of document by the appropriate symbols as indicated on the document under MPO Standard ST. 16 if possible. Applicant is to place a check mark here if English language Translation is attached.

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Traisation is attached.

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Substitute for form 1449B/PTO				Complete if Known		
•	RMATION DI	601	OCUBE	Application Number	10/553,135	
		_		Filing Date	October 14, 2005	
STATEMENT BY APPLICANT				First Named Inventor	Giampiero de Luca	
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Sheet	2	of	3	Attorney Docket Number	SER-104	

		NON PATENT LITERATURE DOCUMENTS	
Examiner Initials*	Cite No. 1	Include name of the author (in CAPITAL LETTERS), title of the article, (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T <sup>2</sup>
	R1	CINATL, J. et al. "Treatment of SARS with human interferons", The Lancet, July 26, 2003, pp. 293-294, Vol. 362.	
	R2	CLEGG, A. et al. "Immunomodulatory drugs for multiple sclerosis: a systematic review of clinical and cost effectiveness", Exp. Opin. Pharmacother., 2001, pp. 623-639, Vol. 2, No. 4.	
	R3	DERYNCK, R. et al. "Isolation and structure of a human fibroblast interferon gene", Nature, June 19, 1980, pp. 542-547, Vol. 285.	
	R4	DROSTEN, C. et al. "Identification of a Novel Coronavirus in Patients with Severe Acute Respiratory Syndrome", <i>The New England Journal of Medicine</i> , April 10, 2003, pp. 1-10, retrieved from www.nejm.org.	
	R5	FAMILLETTI, P.C. et al. "A Convenient and Rapid Cytopathic Effect Inhibition Assay for Interferon", Methods in Enzymology, pp. 387-394, Vol. 78.	
	R6	KSIAZEK, T.G. et al. "A Novel Coronavirus Associated with Severe Acute Respiratory Syndrome", The New England Journal of Medicine, April 10, 2003, pp. 1-12, retrieved from www.nejm.org.	
	R7	MARK, D.F. et al. "Site-specific mutagenesis of the human fibroblast interferon gene", Proc. Natl. Acad. Sci. USA, September 1984, pp. 5662-5666, Vol. 81.	
	R8	MCCORMICK, J.B. et al. "Lassa Fever- Effective Therapy with Ribavirin", The New England Journal of Medicine, January 2, 1986, pp. 20-26, Vol. 314.	
	R9	PESTKA, S. et al. "Interferon Standards and General Abbreviations", Methods in Enzymology, 1986, pp. 14-23, Vol. 119.	
	R10	RUBINSTEIN, S. et al. "Convenient Assay for Interferons", Journal of Virology, February 1981, pp. 755-758, Vol. 37, No. 2.	
	R11	SHEPARD, H.M. <i>et al.</i> "A single amino acid change in INF-β <sub>1</sub> abolishes its antiviral activity", <i>Nature</i> , December 10, 1981, pp. 563-565, Vol. 294.	
	R12	TOGO, Y. et al. "Chemoprophylaxis and Therapy of Respiratory Viral Infections: Double-Blind Clinical Assessment of Ribarvirin (Virazole) in the Prevention of Induced Infection with Type B Influenza Virus", <i>The Journal of Infectious Diseases</i> , June 1976, pp. A109-A113, Vol. 133, Supplement.	
	R13	STUDY GROUP, "Randomised double-blind placebo-controlled study of interferon β-1a in relapsing/remitting multiple sclerosis", <i>The Lancet</i> , November 7, 1998, pp. 1498-1504, Vol. 352.	

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Examiner	Date
Signature	Considered
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Applicant's unique citation designation number (optional). Applicant is to place a check mark here if English language Translation is attached.

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Substitute for form 1449B/PTO				Complete if Known		
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				Filing Date	October 14, 2005	
STATEMENT BY APPLICANT				First Named Inventor	Giampiero de Luca	
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		NON PATENT LITERATURE DOCUMENTS	
Examiner Initials*	Cite No. <sup>1</sup>	Include name of the author (in CAPITAL LETTERS), title of the article, (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T²
	R14	HIGGINS, P.G. <i>et al.</i> "Intranasal Interferon as Protection Against Experimental Respiratory Coronavirus Infection in Volunteers", <i>Antimicrobial Agents and Chemotherapy</i> , November 1983, pp. 713-715, Vol. 24, No. 5.	
	R15	Database SCISEARCH 'Online!, Accession No. 2002:896651; TRUYEN, U. et al. "Antiviral Potency of interferon-omega (IFN-omega) against selected canine and feline viruses", <i>Praktische Tierarzt</i> , October 1, 2002, pg. 862, Vol. 83, No. 10., XP002252700.	
	R16	Database BIOSIS 'Online!, Accession No. PREV200100181684; HABERSETZER, F. et al. "A pilot study of recombinant interferon beta-1a for the treatment of chronic hepatitis C", <i>Liver</i> , December 2000, Abstract only, Vol. 20, No. 6., XP002252701.	
	R17	Database SCISEARCH 'Online!, "Treatment of SARS with human interferons", <i>Lancet</i> , July 26, 2003, Vol. 362, No. 9380, XP002252699.	
	R18	Database WPI, Section Ch, Week 200315, Derwent Publications LTD., London, GB; Class B04, AN 2003-150867, Abstract only, XP002252702.	
	R19	HULTGREN, C. et al. "The antiviral compound ribavirin modulates the T helper (Th) 1/Th2 subset balance in hepatitis B and C virus-specific immune responses", Journal of General Virology, 1998, pp. 2381-2391, Vol. 79.	
	R20	TAM, R.C. et al. "Ribavirin polarizes human T cell responses towards a Type 1 cytokine profile", Journal of Hepatology, 1999, pp. 376-382, Vol. 30.	
	R21		
	R22		
	R23		
	R24		
	R25		
	R26		

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